

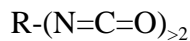
APPENDIX A

ISOCYANATE CHEMICAL CATEGORY

Category: Diisocyanates

Human Health

Definition. Any molecular structure containing two or more isocyanate groups is considered to be a member of the category for new chemical purposes:



Members of the class include new isocyanate monomers as well as new oligomers, polymers, prepolymers, or reaction products of existing isocyanate monomers. Most new chemical diisocyanates of concern are polymers or oligomers containing well-known diisocyanate monomers such as toluene diisocyanate (TDI) or 4,4'-methylenediphenyl diisocyanate (MDI).

Hazard Concerns. Diisocyanates are of concern for potential dermal and respiratory sensitization, and for pulmonary toxicity. Based on conflicting animal and human data for respiratory sensitization, the Agency has determined that there is presently not a reliable animal model for testing diisocyanates for potential respiratory sensitization. At this time, it is assumed that all diisocyanates may be potential human respiratory sensitizers.

Most members of the diisocyanate category have not been tested for carcinogenic potential. Though the aromatic diisocyanates [MDI, TDI, dianisidine diisocyanate (DADI)] tested positive and one aliphatic diisocyanate [hexamethylene diisocyanate (HDI)] tested negative in one species, it is premature to make any generalizations about the carcinogenic potential of aromatic versus aliphatic diisocyanates.

Boundaries. Structures with an isocyanate equivalent weight of $\geq 5,000$ are presumed not to pose a hazard under any conditions. Typically, concerns are confined to those species with molecular weights $< 1,000$.

Frequently, new chemical isocyanates are manufactured with a significant excess of isocyanate monomer. Under these circumstances, the excess monomer is usually regarded as more hazardous than the "new" chemical component, and these PMN substances are ordinarily not regulated under §5 of TSCA. For the purposes of risk assessment within the New Chemicals Program, a PMN substance is considered "existing" if more than 50% of the free isocyanate groups in the PMN substance (new chemical component + existing chemical monomer) reside on unreacted monomer(s). This does not relieve a Company, however, of any obligations to submit a PMN for the new chemical isocyanate if indeed it is not listed on the TSCA Inventory.

General Testing Strategy. The following testing is recommended to address the potential for pulmonary toxicity and dermal sensitization.

1. Dermal sensitization (OPPTS 870.2600).
2. 90-day Subchronic inhalation toxicity test in rodents (OPPTS 870.3465).

In addition, appropriate hazard communication needs to be developed and implemented.

Health and Safety Information. The following information provides guidance in developing hazard communication and protective measures language to accompany new diisocyanate chemicals and formulations. It is based on the Agency's current understanding of the hazards associated with diisocyanates and the most effective means to limit exposure.

Warnings. Exposure to diisocyanates may cause the following human health effects: skin irritation and allergic reactions, respiratory irritation, respiratory sensitization, and lung toxicity; some diisocyanates also may cause cancer. The likelihood that these effects will occur depends on a number of factors; among them, the level of exposure, frequency of exposure, part of the body exposed, and sensitivity of the exposed individual.

Symptoms of allergic reaction and respiratory sensitization include rashes, cough, shortness of breath, asthma, chest tightness and other breathing difficulties. There is uncertainty as to the mechanism by which sensitization occurs. In sensitized individuals, exposure to even small amounts of diisocyanates (below government-recommended workplace exposure levels) may cause allergic respiratory reactions like asthma and severe breathing difficulties. It is especially important to note that contact with skin may lead to respiratory sensitization or cause other allergic reactions. In some cases, the effects of diisocyanate exposure may be immediate and life-threatening; in others, the effects may be delayed and occur hours after the exposure has ended. Repeat or prolonged exposure to diisocyanates may also cause irritation to eyes, skin, respiratory tract and lungs, as well as adverse chronic lung effects, like decreased lung capacity and function. Individuals experiencing shortness of breath, tightness in the chest or other problems breathing should seek immediate medical attention.

Protective Measures. In workplaces where individuals handle diisocyanates or coatings or other formulations that contain them, an industrial hygiene and safety program should be operative. Important components of this program include: hazard communication and training on safe handling practices; use of efficient and well-maintained application equipment, engineering controls and personal protective equipment; housekeeping procedures including spill prevention and cleanup practices; and, if feasible, means to measure airborne levels of polyisocyanates and diisocyanates.

During spray applications, workers should take precautions to avoid breathing vapors, mists or aerosols. Inhalation exposures should be limited to $<0.05 \text{ mg/m}^3$ as an 8-hour time-weighted average (TWA) for combined polyisocyanates and diisocyanates.² Engineering controls should serve as the first, most effective means of reducing airborne polyisocyanate and diisocyanate concentrations; an appropriate NIOSH/MSHA-approved respirator should be used as a secondary tool to lower exposures. Currently, downdraft spray booths and high-volume low-pressure (HVLP) spray guns appear to offer the most efficient technology to reduce inhalation exposures; a maintenance program should always be used to ensure optimal operating efficiencies. To limit dermal contact, individuals should wear impermeable gloves, protective clothing and goggles or glasses with side shields.

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²0.05 mg/m³ or 0.005 ppm TWA is the American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) for each hexamethylene diisocyanate (HMDI), toluene-2,4-diisocyanate (TDI), and methylene bisphenyl isocyanate (MDI). Also, OSHA has set 0.02 ppm as exposure ceilings for both TDI and MDI.